



November 2, 2017

The Honorable Fred Upton
Chairman
Subcommittee on Energy and Power
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Bobby L. Rush
Ranking Member
Subcommittee on Energy and Power
U.S. House of Representatives
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Upton and Walden and Ranking Members Rush and Pallone:

The Food and Drug Administration (FDA) greatly appreciates the Energy and Commerce Committee's attention to the 2017 hurricane season and your particular focus on Puerto Rico following Hurricane Maria. I appreciated the opportunity to testify last week before the Subcommittee on Oversight and Investigations hearing entitled "Examining HHS' Public Health Preparedness for and Response to the 2017 Hurricane Season."

Thank you for your continued commitment to the recovery of Puerto Rico and your support of FDA's efforts to advance these shared goals.

Medical product manufacturing is a critical part of the Puerto Rican economy. There are more than 80 FDA-registered medical product manufacturers across the island. This industrial base is an important source of jobs and economic vitality for the island and it is a key to Puerto Rico's economic recovery. The manufacturing facilities are also a pivotal source of critical medical products for the entire United States. About 8 percent of all pharmaceuticals used in the United States are manufactured in Puerto Rico. Many sophisticated and critical medical devices are also manufactured on the island. Helping to bring these resources back in operation is an important goal for FDA and for Puerto Rico.

After Hurricane Maria, I visited Puerto Rico and the FDA headquarters on the island. I met with the Governor of Puerto Rico, Ricardo Rossello, to discuss the importance of getting medical product facilities fully back to operation to help Puerto Rico and to help all Americans who need

important medical products made on the island. Since my visit, I have continued to stay in touch with the Governor's team as we advance these efforts.

We are actively working every day to engage with companies to ensure continued operations on the island. Companies are functioning at different levels based on the damage done by Hurricane Maria and on their generator capacity. We are keeping a close watch on the most critical medical products that are at the highest risk for shortage. In urgent cases, when critical products are at issue, we have intervened with government partners such as the Federal Emergency Management Agency and the Department of Homeland Security to help secure fuel to maintain production lines and get clearance to move logistical support onto the island and finished goods to their intended recipients. We are communicating with the firms and, in some cases, are in daily contact with them to help them manage the evolving challenges. We are prepared to act quickly to help prevent drug and device shortages.

The Subcommittee's hearing "The 2017 Hurricane Season: A Review of Emergency Response and Energy Infrastructure Recovery Efforts" is examining a critical component of Puerto Rico's recovery. We share the goal of restoring the island's electrical grid. Restoring the grid is imperative for public health because of the significant medical manufacturing performed in Puerto Rico. To date, FDA has been working on a case-by-case basis with federal and local government partners to provide logistical support and fuel to drug and device companies to enable them to continue operations. Our next priority is to ensure manufacturers get back to stable production as soon as possible to ensure supply of critical products to patients across the United States. Our experts will be working closely with local and federal partners to prioritize a small subset of critical facilities—plants that manufacture medically important products that are sourced primarily or only in Puerto Rico—for consideration for earlier access to the rebuilt grid. Most facilities can only engage partial production on generators. Over time, and for a subset of facilities, our work to avert shortages might entail helping them to get back closer to full production.

Thank you again for the opportunity to testify before your committee. Best wishes for a successful hearing, and please let me know if I can be of assistance on this or any other issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Gottlieb", followed by the letters "MD" in a slightly larger, bolder font.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs